

CIC exempts clinical trial related information from disclosure under RTI Act

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With a view to protect patient related information and preserve exclusive intellectual property rights of the pharma companies the Central Information Commission (CIC) recently passed a decision acknowledging exemption from disclosure of information on clinical trials under Right to Information (RTI) Act, 2005. The CIC with its latest decision has clearly spelt out what information can be exempted from disclosure in case of clinical trials.

In the present case, a RTI application was filed seeking information on post-licensure HPV vaccination observation study for usage of certain drugs Gardasil and Cervatrix in an age group outside the age group on whom they were tested. The applicants' intention was to verify whether the licensing authorities had verified the data prior to approving the same. It was contented by them that for the transparency and accountability purposes in biomedical research disclosure of information was essential.

CIC while passing its decision said that transparency is essential in biomedical research however, such information may not be divulged in the public domain as it includes several substantial strategic, scientific data along with patient related information.

The decision states, "The problem would persist wherein data are inter-linked and segregation is not possible making it a contesting issue for disclosure of information. However, with regard to clinical trials, patient related data and trade secrets and intellectual property of the pharmaceutical companies may not be disclosed."

According to Gowree Gokhale, partner, pharma and life sciences, Nishith Desai Associates, "It is a landmark decision because through this the Commission has acknowledged the issue of what information is needed to be made public. With this the commission has held that if required the information which needs to be protected can be severed from the overall paper work for clinical trial that is filed with the DCGI's office."

However she informed that though this decision allows severing of information based on its need for confidentiality it is not clear how effectively the same can be achieved, where the confidential and intellectual property related information is very closely interlinked with the other information.

Many in the industry are of the opinion that there is a need for guidelines for such segregation of information other than those exempted under Section 8 of the Act. (Pharnabiz.com)